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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,340	11/23/1999	Graca Raposo	255/013-US	8331

22249 7590 10/10/2002

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 10/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/582,340	Raposo et al.
Examiner	**Art Unit**
G.R. Ewoldt	1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *3/21/02 and 7/31/02*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15 and 17-29* is/are pending in the application.

4a) Of the above, claim(s) *2, 3, 6, 8-15, 17-19, and 22-29* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4, 5, 7, 20, and 21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *notice to comply*

Application No.: 09/582,340

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [ ] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: improper species

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

DETAILED ACTION

1. Newly submitted Claims 22-29 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: the invention under examination comprises a method of stimulating an immune response comprising administering to a mammal a lactadherin. Newly submitted claims 22 and 24-26 recite a method comprising administering a fusion protein comprising a lactadherin fused to an additional antigen such as a viral or bacterial protein. Newly submitted claims 22 and 27-29 recite a method comprising administering a nucleic acid encoding a lactadherin, i.e., gene therapy. The above mentioned three methods are patentably distinct

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 22-29 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 1, 4, 5, 7, 20, and 21 are drawn to the elected invention and are being acted upon.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, the specification continues to disclose SEQ ID NO:1 as comprising amino acids (see for example page 7, paragraph 3). Applicant's assertion in Paper No. 13, filed 7/31/02 that "SEQ ID NO.1 AND SEQ ID NO.3 comprise nucleotide sequences and amino acid sequences" is simply in error. See line <212> of the Sequence Listings which indicates that the sequences consist of DNA. Note that while a Sequence Listing may disclose the amino acid translation of a nucleotide sequence under the DNA sequence, a SEQ ID NO: itself consists of either DNA or protein. Additionally, the amended Sequence Listing discloses that SEQ ID NOS: 3 and 4 comprise the species "Marine." Note that marines are not recognized as a unique species.

4. In view of Applicant's amendment and response, filed 3/21/02, the rejections under the first paragraph of 35 U.S.C. 112 have been withdrawn.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-5, 7, and newly added Claims 20-21, stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,505,955 (of record), for the reasons of record as set forth in Paper No. 10, mailed 11/21/01.

Applicant's arguments, filed 3/21/02, have been fully considered but they are not persuasive. Applicant argues that "USP 5,505,955 essentially relates to non-immunologic methods of treating diarrhea. The proposed method is based on the property of a biological material or complex to bind specifically to rotaviruses, thereby inhibiting rotavirus infection....This is in clear contrast with the claimed invention, which relates to the stimulation of an immune response against antigens, not to the inhibition of virus infection." Applicant is advised that the mechanisms by which the method of the prior art function are irrelevant. The prior art teaches the administration of the same composition as that recited in the instant claims (lactadherin); stimulation of an immune response would simply comprise an inherent property of said administration.

Applicant argues that "The Examiner's citation and quotation of Application of Best, 562 F.2d 1252, 1255 (CCPA 1977) is inapposite....The actual method claims at issue in Best were only rejected because the court found that "all process limitations of [the] claim [ ] are expressly disclosed ..." and that the missing element was disclosed through inherency." It remains the Examiner's position that this finding is appropriate in the instant case, all limitations (administration steps) are disclosed and Applicant's further characterization (of mechanism) are inherent properties.

7. Claims 1, 4-5, 7, and newly added Claims 20-21, stand rejected under 35 U.S.C. 102(b) as being anticipated by WO95/15171 (of record), for the reasons of record as set forth in Paper No. 10, mailed 11/21/01.

Applicant's arguments, filed 3/21/02, have been fully considered but they are not persuasive. Applicant argues that "WO 95/15171 relates essentially to the same disclosure as USP 5,505,955," and presents arguments essentially the same as the arguments regarding the rejection under the '955 patent. See the Examiner's response regrading the inherent properties of the method in paragraph 6 above.

8. The following are new grounds for rejection necessitated by Applicant's amendment.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 4-5, 7, and newly added Claims 20-21 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) in Claim 1 and 21, the recitation of "a lactadherin or a fragment thereof, said fragment comprising a functional integrin binding site of lactadherin,"

B) in Claim 7, the recitation of the method of claim 3 "lactadherin or fragment thereof."

Applicant has not asserted that the amendments do not comprise new matter and no support for the changes has been found in the specification.

11. This application contains claims drawn to inventions nonelected with traverse in Paper No. 9. A complete reply to the

final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center at (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 25, 2002

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600